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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,389	12/13/2005	J Michael Palmowski	0380-P03220US1	2535

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DANN, DORFMAN, HERRELL & SKILLMAN
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SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,389	PALMOWSKI ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 38-45* is/are pending in the application.

4a) Of the above claim(s) *3-6, 8, 9, 11, 12, 15-30, 38 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,10,13,14,39-41 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/13/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are examined on the merits. Claims 3-6, 8, 9, 11, 12, 15-30, 38 and 42 remain withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/09 has been entered.

Response to Arguments

Applicant's arguments filed 6/29/09 have been fully considered but they are not persuasive. See responses below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(New Rejection Necessitated by Amendments) Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rovinski et al.

(US PGPub 2002/0051770 A1) and Esslinger et al. (Journal of Clinical Investigation, 2003).

The claimed invention is drawn to a method of stimulating an immune response to an antigen in an individual by a heterologous prime-boost immunization protocol, the method comprising the steps of:

i) administering to the individual a plasmid or other expression vector, which encodes said antigen to prime said immune response;

ii) administering to the individual a lentivirus engineered to comprise exogenous nucleic acid encoding said antigen to boost the primed immune response. The exogenous nucleic acid encodes a pathogen-derived antigen, such as a lentiviral antigen. The claimed invention also includes a method of administering lentivirus particles, which encode said antigen, to an individual in order to boost a pre-existing immune response that was elicited by the administration of a nucleic acid also encoding said antigen. However, for purposes of examination, this alternative method involving the boosting of a pre-existing immune response is interpreted to be within the same scope as that of the prime/boost method of claim 1. The lentivirus is infectious but replication deficient.

Rovinski et al. teach a prime-boost method of inducing an antibody response to HIV antigens, particularly the envelope glycoprotein. In order to induce such an immune response, Rovinski et al. teach to prime with plasmids encoding the envelope glycoprotein, and then boost with non-infectious, non-replicating HIV-like particles (VLPs) that encode this envelope glycoprotein. Rovinski et al. also teach that in creating the VLPs, certain genes/proteins can be modified or may be obtained from different HIV isolates. For example, Rovinski et al. teach that the ENV gene from the BX08 isolate can

be employed in VLPs and that the GAG and POL gene of a modified HIV genome (which is used to make VLPs) can originate from the same or different isolates. However, Rovinski et al. do not teach the use of an infectious, non-replicating lentivirus. *See abstract and paragraphs [5, 10, 11, 17-20, 40 and 41].*

Esslinger et al. teach the use of an infectious, replication deficient lentivirus in prime-boost method in order to determine if two administrations of the same vector/vaccine causes antivector immunity against the second administration. Esslinger et al. determined that such immunity was present. *See pages1674 and 1680.*

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Rovinski et al. in order to use lentivirus that is infectious but can't replicate in a heterologous prime-boost method. One would have been motivated to do so, given the suggestion by Rovinski et al. that the method be used to immunize an individual with a heterologous prime boost protocol involving a lentivirus VLP. There would have been a reasonable expectation of success, given the knowledge that infectious non-replicating lentiviruses can be used in a prime-boost protocol as long as it is a heterologous prime-boost protocol, as taught by Esslinger et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to arguments:

Applicants argue that Rovinski et al. do not teach the use of an infectious, non-replicating lentivirus in a heterologous prime-boost immunization protocol.

In response, while it is acknowledged that Rovinski et al. fail to teach an infectious, non-replicating lentivirus, Esslinger et al. has established that such a virus can be used in a prime-boost method, as set forth in the obviousness rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648